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TO:	FROM:
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COMPANY:	DATE:
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RE:	APPLICATION SERIAL NUMBER:
Response to Restriction Requirement dated March 16, 2007	10/826,925

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CENTRAL FAX CENTER****APR 16 2007****PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Kenneth T. Heruth; Confirmation No. 1024  
Keith A. Miesel  
Serial No.: 10/826,925  
Filed: April 15, 2004 Customer No.: 28863  
Examiner: Patricia C. Mallari  
Group Art Unit: 3735  
Docket No.: 1023-350US01  
Title: COLLECTING SLEEP QUALITY INFORMATION VIA A MEDICAL  
DEVICE

CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via facsimile to the United States Patent and Trademark Office on April 16, 2007.

By: 

Name: Patricia Cygan

**RESPONSE TO RESTRICTION AND ELECTION REQUIREMENTS**

Commissioner for Patents  
Alexandria, VA 22313-1450

Dear Sir:

In the Office Action mailed March 16, 2007, the Examiner issued both Restriction Requirements and Election Requirements. The Restriction and Election Requirements are addressed separately below.

***Restriction Requirements***

- (1) The Office Action restricted claims 1-99 under 35 U.S.C. § 121 as follows:
- I. Claims 1-23 and 69-82, drawn to a method, classified in class 600, subclass 300;
  - II. Claims 24-68, 83-99, drawn to a system or device, classified in class 600, subclass 300.

Applicant elects Group II without traverse.

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- (2) The Office Action also restricted claims 24-68 and 83-99 under 35 U.S.C. § 121 as follows:

- IIa. Claims 24-56 and 83-99, drawn to a system, classified in class 600, subclass 300;
- IIb. Claims 57-68, drawn to a programming device or computer readable medium comprising instructions for the programming device, classified in class 607, subclass 1.

Applicant elects Group IIa without traverse.

### ***Election Requirements***

The Office Action identified and required election between numerous groups of patentably distinct species, as set forth below. Applicant respectfully traverses each of the election of species requirements, for the reasons discussed below the following listing of the numerous species election requirements.

- (1) The Office Action stated that the application contains claims directed to the following patentably distinct species:
- A. A method or apparatus wherein monitoring at least one physiological parameter comprises monitoring at least one of activity level, posture, heart rate, respiration rate, respiratory volume, and core temperature;
  - B. A method or apparatus wherein monitoring at least one physiological parameter comprises monitoring at least one of blood pressure, blood oxygen saturation, partial pressure of oxygen within blood, partial pressure of oxygen within cerebrospinal fluid, muscular activity, arterial blood flow, melatonin level within a bodily fluid, and galvanic skin response.

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- (2) The Office Action also stated that the present application contains claims directed to the following patentably distinct species:
- A1. A method or apparatus wherein the sleep quality metric comprises sleep efficiency;
  - A2. A method or apparatus wherein the sleep quality metric comprises sleep latency.
- (3) The Office Action also stated that the application contains claims directed to the following patentably distinct species:
- B1. A method or apparatus wherein activity level or a signal that varies as a function of activity is monitored;
  - B2. A method or apparatus wherein posture or a signal that indicates posture is monitored;
  - B3. A method or apparatus wherein melatonin level within bodily fluid or a signal that varies as a function of a level of melatonin within the bodily fluid of a patient is monitored.
- (4) The Office Action also stated that the application contains claims directed to the following patentably distinct species:
- C1. A method or apparatus wherein identifying when the patient is asleep is based on at least one of activity level, heart rate, respiration rate, respiratory volume, and core temperature;
  - C2. A method or apparatus wherein identifying when the patient is asleep is based on at least one of blood pressure, blood oxygen saturation, partial pressure of oxygen within blood, partial pressure of oxygen within cerebrospinal fluid, muscular activity, arterial blood flow, melatonin level within a bodily fluid, and galvanic skin response.

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- (5) The Office Action also stated that the application contains claims directed to the following patentably distinct species:
- D1. A method or apparatus wherein determining the value of the sleep quality metric comprises determining an amount of time that the patient is asleep during a period;
  - D2. A method or apparatus wherein determining the value of the sleep quality metric comprises identifying at least one of a number of arousal events and a number of apnea events during a period of sleep;
  - D3. A method or apparatus wherein determining the value of the sleep quality metric comprises determining an amount of time that the patient was within the sleep state.
- (6) The Office Action also stated that the application contains claims directed to the following patentably distinct species:
- E1. A method or apparatus wherein a graphical representation of the quality metric is presented;
  - E2. A method or apparatus wherein a message related to sleep quality is presented.
- (7) The Office Action also stated that the application contains claims directed to the following patentably distinct species:
- F1. A method or apparatus wherein the processor that determines a value of the metric indicative of sleep quality comprises a processor of the medical device;
  - F2. A method or apparatus wherein the processor that determines a value of the metric indicative of sleep quality comprises a processor of the programming device.

Applicant respectfully traverses each of these election of species requirements. Applicant agrees with the conclusion that the various species are patentably distinct. However, Applicant respectfully submits that the requirement of restriction between the species is improper.

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MPEP 806.04(f) states that a requirement of restriction to one of a plurality of identified species may be proper if the species are mutually exclusive. The species identified in the Office Action are not mutually exclusive. For each election requirement, the identified species are disclosed by Applicant as being usable together.

For example, the application discloses that monitoring at least one physiological parameter to, for example, identify when the patient is asleep, may comprise monitoring any one or more of activity level, posture, heart rate, respiration rate, respiratory volume, core temperature, blood pressure, blood oxygen saturation, partial pressure of oxygen within blood, partial pressure of oxygen within cerebrospinal fluid, muscular activity, arterial blood flow, melatonin level within a bodily fluid, and galvanic skin response. (*E.g.*, paragraph [0006]). Similarly, the application discloses that both sleep efficiency and sleep latency may be monitored in some embodiments. (*E.g.*, paragraph [0053]). The application discloses that embodiments may monitor any one or more of activity, posture, and melatonin level. (*E.g.*, paragraph [0072]). As another example, the application discloses that embodiments may determine any one or more of time asleep during a period, number of arousals or apneas, and time within sleep state. (*E.g.*, paragraph [0100]).

In sum, the application discloses that the various species are usable together and, therefore, not mutually exclusive species for which election may be required.

Furthermore, MPEP 806.04(b) states that where species are related the question of restriction must be determined by both the practice applicant to election of species and the practice application to other types of restrictions, such as those covered in MPEP 806.05 – 806.05(j). The Office Action has set forth no basis for restriction as between any of the identified species under MPEP 806.05 – 806.05(j). Accordingly, for this additional reason, the restriction between the identified species is improper.

Applicant elects species A, A1, B1, C1, D3, E1 and F1, with traverse, for the reasons discussed above.

Applicant submits that claims 1, 2, 4-25, 27-73, 75, 77-87, 89 and 91-99 are readable on species A.

Applicant submits that claims 1-4, 6-27, 29-77, 79-91 and 93-99 are readable on species A1.

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Applicant submits that claims 1-70, 72, 73, 75-84, 86, 87 and 89-99 are readable on species B1. Claims 72 and 86 are readable on species B1 because the accelerometer signals monitored according to those claims vary as a function of activity of the patient. Claims 72 and 86 depend from claims 71 and 85, which, therefore, must also be examined as linking claims (MPEP 809).

Applicant submits that claims 1-75, 77-89 and 91-99 are readable on species C1.

Applicant submits that claims 1-5, 8-28 and 31-99 are readable on species D3.

Applicant submits that claims 1-14, 16-36, 38-53, 55-59, 61-65, 67-81, 83-95 and 97-99 are readable on species E1.

Applicant submits that claims 1-43 and 45-98 are readable on species F1.

Accordingly, Applicant submits that claims 1, 2, 4, 8-14, 16-25, 27, 31-36, 38-43, 45-53, 55-59, 61-65, 67-70, 72, 73, 75, 77, 79-81, 83, 84, 86, 87, 89, 91, 93-95, 97 and 98 are readable on the combination of species A, A1, B1, C1, D3, E1 and F1 elected by Applicant. Furthermore, claims 71 and 85 must also be examined as linking claims for claims 72 and 86.

Additionally, because Applicant has elected Groups II and IIa (claims 24-56 and 83-99) in response to the restriction requirements above, claims 24, 25, 27, 31-36, 38-43, 45-53, 55, 56, 83-87, 89, 91, 93-95, 97 and 98 are effectively elected (with traverse) for further prosecution on the merits

Please charge any additional fees or credit any overpayment to deposit account number 50-1778.

Date:

By:

April 16, 2007  
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